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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROBERTS, DARIN	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,776	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	Darin R. Roberts	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 9, 10, 22, 25-27, & 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruse et al. (US 6201993 B1).

In reference to ***claims 1, 10, 22, 25, 26, 27, & 28***, the Kruse et al. patent teaches the use of an implantable device that can be a pace maker or a defibrillator (see abstract and column 1, lead lines 20-27) and because by definition an electrogram is a tracing of the electrical potentials of a tissue (as the brain or heart) made by means of electrodes placed directly in the tissue instead of on the surface of the body, the Kruse et al. device is inherently capable of detecting electrograms (see column 8, lead lines 52-55 & column 11, lead lines 7-13). Kruse et al. also teaches the use of pacing circuitry to deliver pacing pulses as well as a processor coupled to a sensing circuit and a pacing circuit (see column 8, lead lines 42-42 & lead lines 52-58). Kruse et al. teaches the use

of a cardiac monitor that is upgradeable via a programmer (see column 3, lead lines 2 – 7) and a device capable of being programmed to detect far-field electrogram signals (see column 4, lead lines 54-56). The Kruse et al. patent teaches a device that is linked to an implanted device via telemetry (see abstract) and the use of leads that incorporate the use of detector referred to as sensors (see column 8, lead lines 53-55). The Kruse et al. patent also teaches the use of an adaptor referred to as a lead that must inherently possess a connector, and the CRM device of the Kruse et al. patent must inherently possess a header for attaching to a lead (see column 8, lead lines 52-55). T

In reference to ***claim 2***, the Kruse et al. patent teaches an apparatus comprises a band-pass filter (see column 14, lead lines 54-56 & column 15, 44-49).

In reference to ***claims 6 & 8***, the Kruse et al. patent teaches the use of microprocessor in conjunction with RAM (Random Access Memory) for storing a variety of programmed-in operating mode and parameter values that are used by the operating system. Kruser et al. also teaches that the RAM may also be used for storing data compiled from sensed cardiac activity and/or relating to operating history for telemetry out on receipt of a retrieval or interrogation instruction (see column 8, lead lines 64-68 & column 9, lead lines 1-3).

In reference to ***claims 7 & 9***, the Kruse et al. patent teaches the use of activity sensors to detect and assess the activity levels of the user (see column 8, lead lines 58-63).

In reference to ***claim 9***, the Kruse et al. patent teaches the use of an arrhythmia detection means (see column 1, lead lines 21-27).

Claim 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sluetz et al. (US 4662382 A).

In reference to ***claims 11-15***, the Sluetz patent teaches the use of an adaptor referred to as a lead (see abstract) capable being attached to a cardiac rhythm management (CRM) device (see abstract). The lead of the Sueltz et al. device possesses a means for sensing far-field signals (see abstract) referred to as an electrode, Sueltz et al. also teaches the use of leads that are detachable and that possesses connectors which connect them to a CRM device (see column 1, lead lines 36-39). The lead of the Sueltz et al. device is kept in contact with the desired heart tissue via an anchor (see fig. 2) thus allowing it to better detect far-field signals in a desired region, and also possesses multiple sensors (see abstract). A CRM device connecting to the Sluetz et al device must inherently possess a header for attaching to a lead

Claims 16, 17, 20, 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bocek et al. (US 6889079 B2).

In reference to ***claim 16, 17, 20, & 21***, the Bocek et al. patent teaches an implantable medical device programmer, comprising a device configuration module adapted to generate instructions for configuring an implantable medical device into one of an implantable cardiac monitor and an implantable pacemaker (see abstract and column 11, lead lines 40-45). Bocek et al. also teaches the use of a telemetry module coupled to a device configuration module, the telemetry module including a telemetry

transmitter to transmit the instructions to the implantable medical device and a telemetry receiver to receive physiological data acquired by and transmitted from the implantable medical device. The telemetry device is inherently capable of near field and far field communication (see column 9, lead line 11-22). The Bocek et al. device teaches a data analyzer including at least one detector to detect a predetermined condition (such as arrhythmia) from the physiological signal (see column 6, lead lines 24-27). It also teaches a device configuration module that generates instructions for configuring the implantable medical device into the implantable pacemaker in response to the detection of a predetermined condition (see column 9, lead line 23-38 & Table 1).

Claims 16, 18, 19, 20, & 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al. (US 6925326 B2).

In reference to ***claim 16, 18, 19, 20, & 21***, the Bocek et al. patent teaches an implantable medical device programmer, comprising a device configuration module adapted to generate instructions for configuring an implantable medical device into one of an implantable cardiac monitor and an implantable pacemaker (see column 12, lead lines 18-23 & column 15, lead lines 8-15). Bocek et al. also teaches the use of a telemetry module coupled to a device configuration module, the telemetry module including a telemetry transmitter to transmit the instructions to the implantable medical device and a telemetry receiver to receive physiological data acquired by and transmitted from the implantable medical device. The telemetry device is inherently capable of near field and far field communication (see column 7, lead line 30-37). The

Bocek et al. device teaches a data analyzer including at least one detector to detect a predetermined condition (such as arrhythmia) from the physiological signal (see column 8, lead lines 25-36). It also teaches a device configuration module that generates instructions for configuring the implantable medical device into the implantable pacemaker in response to the detection of a predetermined condition (see column 12, lead lines 18-23 & column 15, lead lines 8-15).

Claims 29, 32-37, 40, 42, 43, 46-51, 54, & 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (US 5439481 A).

In reference to ***claims 29, 32-37, 40, 42, 43, 46-51, & 54, 56***, the Adams patent teaches a computer or computer-based system capable of generating instructions readable by an implantable cardiac monitor, the instructions upgrading the implantable cardiac monitor to an implantable pacemaker (see column 4, lead lines 57-63), including programming a sensing circuit for sensing an intracardiac electrogram, and transmitting the instructions to the implantable cardiac monitor via a wireless system (see column 4, lead lines 57-63), thus the Adams device must inherently possesses an algorithm to that is sent to the implantable device to alter the implantable device's function. The Adams patent also teaches sending signals back and forth between the implanted device and the external device (see column, 4, lead lines 63-68), as well as the automatic or manual triggering of cardioversion implying that the Adams device is inherently capable of analyzing detect arrhythmic behavior in automatic mode (see column 5, lead lines 1-16). The Adams however the Adams patent does not teach placing such processes on

to a computer readable medium. The Adams patent also inherently teaches the use of a computer readable medium because the memory of the device is capable of being read by a computing means within the Adams device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5, *23 & 24,* are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. (US 6201993 B1).

In reference to ***claim 3***, the Kruse et al. patent teaches the use of a single band pass filter (see column 14, lead lines 54-56 & column 15, 44-49), however it does not teach the use of two band-pass filters.

Thus it would have been obvious to one of ordinary skill in the art to incorporate the use of a second filter to broaden the range of acceptable signal frequencies

In reference to ***claims 4 & 5***, the Kruse et al. device teaches the use of a band pass filters possessing particular cut-off frequencies, however Kruse does not teach placing a first low cut-off frequency within the range of 10 Hz to 30 Hz and placing a second high cut-off frequency in a range of 60 Hz to 150 Hz.

However it would have obvious to one of ordinary skill in the art to adapt or adjust the cut off frequencies to optimize treatment.

In reference to ***claim 23 & 24***, the Kruse et al device teaches the use of one electrode in conjunction with a sensor and an adaptor referred to as a lead, however the Kruse patent does not teach the use of multiple electrodes in conjunction with said adaptor.

However it would have been obvious to one of ordinary skill in the art to incorporate the use of multiple electrodes to broaden or expand the range within which the device is stimulating.

Claims 30, 31, 38, 39, 41, 44, 45, 52, 53, & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (US 5439481 A).

In reference to ***claims 30, 38, 44 & 52***, the Adams patent does not explicitly teach the use of the use of band-pass filter however the use of such filters are quite common in the art of cardiac stimulation and it would have been obvious to one of ordinary skill in the art to incorporate the us of a band-pass filter into the Adams device to do away with undesirable input signals and in turn reduce the occurrence of improper stimulation.

In reference to ***claim 31, 39, 45 & 53***, the Adams patent does not explicitly teach the "reallocation" of memory spaces, however such a process of allocation is know to the art of implantable devices, and thus it would have been obvious to one of ordinary skill in the art reallocate memory spaces to allow for optimal information storage.

In reference to ***claim 33***, the Adams patent does not explicitly teach the storing of algorithms within the implantable device however it would have been obvious to one

of ordinary skill in the art to store such algorithms with in the implantable device to provide the external programming device with

In reference to ***claims 41 & 55***, the Adams device does not teach the storage of date and times of cardiac events, however the recording and storage of such events is well known in the art, and thus it would have been obvious to one of ordinary skill in the art to incorporate the use of such a storage technique to allow a medical practitioner to determine if any abnormal occurrences exist in an individual's cardiac patterns.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner wishes to cite **Stein et al. (US 6636963 B1)** because of its reference to the allocation of memory and the use of such allocation methods in conjunction with an implantable device and an external programmer for said implantable device. The examiner would also like to cite **Dirnberger et al. (US 6589187 B1)** because of its reference to the allocation of memory and the use of such allocation methods in conjunction with an implantable device and an external programmer for said implantable device, and its reference to the storage of dates and times associated with cardiac events.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/17/06

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